

## REMARKS

By this Office Action, the Examiner has required restriction to one of the following inventions:

I. Claims 20-26, drawn to ONE isolated nucleic acid, a vector thereof, and cultured cell, classified in class 536, subclass 23.1; class 435, subclasses 69.1, 320.1, 325.

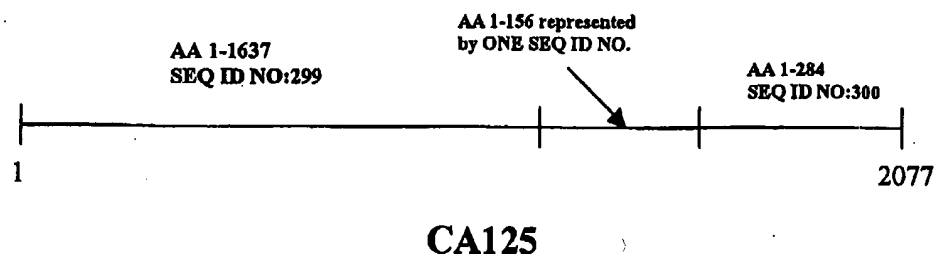
**(Upon election of Group I above, Applicant must further elect ONE nucleic acid from those listed in Claim 20, part a, and ONE corresponding encoded polypeptide from those listed in Claim 21, part a, as each sequence represents a separate invention, not a species. Additionally, Claim 26 will only be examined to the extent it reads on the elected sequence(s).)**

II. Claims 14-19, 27, 30-33 drawn to ONE purified polypeptide, classified in class 530, subclass 350; class 424, subclass 184.1.

**(Upon election of Group II above, Applicant must further elect ONE polypeptide sequence from those listed in Claim 27, part a, as each sequence represents a separate invention, not a species. Claims 14-19 will only be examined to the extent they read on the elected sequence.)**

III. Claims 1-12, drawn to ONE CA125 molecule comprising an extracellular domain of SEQ ID NO.: 299, ONE repeat domain, and ONE cytoplasmic domain comprising SEQ ID NO.: 300, classified in class 530, subclass 350.

**(Upon election of Group III, Applicant must further elect ONE multiple repeat domain corresponding to ONE linear sequence identifier comprising amino acids 1-156 of domains 1-5. For example, upon election, of Group III, a search and examination of a 2077 AA polypeptide will take place as set forth below:**



IV. Claim 13, drawn to a CA125 molecule comprising SEQ ID NO.: 162, classified in class 530, subclass 350.

V. Claims 28-29 drawn to a purified antibody that binds to ONE polypeptide, classified in class 530, subclass 387.1.

**(Upon election of Group V above, Applicant must further elect ONE polypeptide sequence from those listed in Claim 28, part a, as each sequence represents a separate invention, not a species.)**

VI. Claim 34, drawn to ONE antisense molecule, classified in class 800, subclass 286.

**(Upon election of Group VI above, Applicant must further elect ONE nucleic acid from those listed in Claim 20, part a, as each sequence represents a separate invention, not a species.)**

Responsive to the Requirement for restriction, Applicant elects to prosecute the invention of group III, with traverse Claims 1-12 drawn to one polypeptide. The applicant elects the repeat domain as shown in SEQ ID NO. 150 for examination.

Applicants respectfully request reconsideration of the Requirement for Restriction, or in the alternative, modification of the Restriction Requirement to allow prosecution of more than one group of Claims designated by the Examiner in the present Application, for the reasons provided as follows.

Under 35 U.S.C § 121 “two or more independent and distinct inventions . . . in one Application may . . . be restricted to one of the inventions.” Inventions are “independent” if “there is no disclosed relationship between the two or more subjects disclosed” (MPEP 802.01).

The term “distinct” means that “two or more subjects as disclosed are related . . . but are capable of separate manufacture, use or sale as claimed, AND ARE PATENTABLE OVER EACH OTHER” (MPEP 802.01) (emphasis in original). However, even with patentably distinct inventions, restriction is not required unless one of the following reasons appear (MPEP 808.02):

1. Separate classification
2. Separate status in the art; or
3. Different field of search.

Further, under patent Office Examining Procedures, “[i]f the Search and Examination of an entire Application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions” (MPEP 803, Rev. 8, May 1988) (emphasis added).

The Examiner’s assertions to the contrary notwithstanding, Applicants respectfully submit that conjoint examination and inclusion of all of the Clams of the present Application would not present an undue burden on the Examiner, and accordingly, withdrawal of the Requirement for Restriction.

With respect to the requirement to elect a single species for examination on the merits, Applicants respectfully traverse this requirement for the following reasons:

I. Claim 1(b) providing the multiple repeat domains does not include a genus species relationship

Claim 1(b) relates to a multiple repeat domain. A CA125 molecule can include a variety, if not all of the repeats in a single molecule. SEQ ID NO: 162 which show the recombinant molecule has been marked up as Appendix Tab A, to show the multiple repeats present in a single molecule. Claims to be restricted to different species must be mutually exclusive. The general test as to when claims are restricted respectively to different species is the fact that one claim recites limitations which under the disclosure are found in a first species, but not in a second, while a second claim recites limitations disclosed only from the second species and not the first. MPEP § 12.0[3][c]. As can be seen from an inspection of the recombinant molecule shown in SEQ ID NO: 162, CA125 molecule within the scope of claim 1(b) may have multiple

repeat domains which are not mutually exclusive. Consequently, Applicants respectfully request examination on the multiple repeat domains as claimed. This requirement to elect a single combination of repeats violates the basic right of the Applicants to claim his invention as he chooses. In re Weber, 580 F.2d 455 (USCC 1978).

II. Restriction is not appropriate if the claims are directed to substantially the same molecule

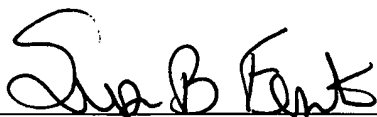
Species are patentably distinct when they are related, but they are capable of separate manufacture and are patentable (novel and nonobvious) over each other. The multiple repeat domains contain multiple repeats wherein each repeat unit has five genomic exons. The variation in repeats set out in Claim 1 (b) are 82% identical and thus present related chemical compounds. The repeat domain is a sequence of 156 amino acids which are repeated multiple times within a discrete portion of the CA125 protein. The repeat domain has its own function and combines with the other domains to provide the overall function of the protein. The designated exons in the repeat domain can vary, but, this variance is minimal. Importantly, when the nucleic acids are expressed they form a CA125 protein. Restriction is not appropriate if claims are directed to the same protein.

In view of the above, withdrawal of the Requirement for the Restriction is requested, and an early action on the merits of the Claims is courteously solicited.

Respectfully Submitted,

BUTLER, SNOW, O'MARA,  
STEVENSON & CANNADA

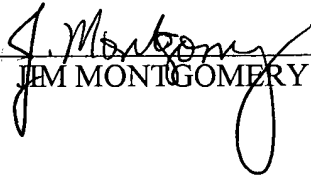
Date: 10-5-03

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JIM MONTGOMERY

MEMPHIS 171783v1

multiple report domain

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164  
A TVPFMVPFTL NFTITNLQYE EDMRHPGSRK

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12151 RPDPEDLGLD <sup>222</sup>RERLYWELSN LTNGIQELGP YTLDRNSLYV <sup>250</sup>NQFTHRSSMP  
12201 <sup>278</sup>TTSTPGTSTV DVGTSGTPSS SPSP <sup>271</sup>  
12251   
12301   
12351 <sup>219</sup>  
12401 <sup>201</sup>LQYGEDMGHP GSRKFNTTER VLOGILGPIF KNTSVGPLYG GCRLTSLRSE  
12451 <sup>234</sup>KDGAATGVDA ICIHHLDPKS PGLNRERLYW ELSQLTNGIK ELGPYTLDRN  
12501 <sup>252</sup>SLYVNCFTHR <sup>280</sup>TSVPTSSTPG TSTVDLGTSG TPFSLPSPAT <sup>202</sup>  
12551 <sup>170</sup>  
12601 <sup>235</sup>  
12651 <sup>267</sup>  
12701 <sup>182</sup>VPFTLNFTIT <sup>202</sup>NLQYEEDMHH PGSRKENTTE RVLOGILGPM FKNTSVGLLY  
12751 <sup>236</sup>SGCRLTLLRS EKDGAATGVD AICTHRLDPK SPGVDRQLY WELSQLTNGI  
12801 <sup>243</sup>KELGPYTLDNR NSLYVNCFTH <sup>283</sup>QTSAPNTSTP GTSTVDLGTS GTPSSLPSPPT  
12851 <sup>170</sup>  
12901 <sup>236</sup>  
12951 <sup>2105</sup>  
13001 <sup>183</sup>  
13051 <sup>202</sup>PMFKNTSVGL <sup>240</sup>LYSGCRLTLL HPEKNGAATG MDAICSHRLD PKSPGLNREQ  
13101 <sup>250</sup>LYWELSOLTH GIKELGPYTL DRNSLYVNCFTHRSSVAPTS TPGTSTVDLG  
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13251 <sup>257</sup>  
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 14551 VOLRTSGTPS SLSSPTIMXX XPLLXPFTLN FTITNLXYEE XMXXPGSRKF <sup>279</sup> <sup>?</sup>  
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 20101 DXXCXXXXDP XXPGLDREX<sup>2</sup>LYWELSXLTX IXELGPYXLD RXS<sup>2</sup>LYVNG<sup>2</sup>F  
 20151<sup>264</sup> HQTFAPNTST<sup>283</sup> PGTSTVDLGT SGT<sup>2</sup>PSSLPSP T<sup>2</sup>SAGPLLVPF TLNFTITNLQ  
 20201<sup>183</sup> YEEDMHPGS RKFNTT<sup>2</sup>ERV L QGI<sup>202</sup>LGPMFKN TSVGLLYSGC RLTL<sup>2</sup>LLR<sup>2</sup>PEKN  
 20251 GAATRVD<sup>2</sup>AVC THRPDPKSPG LDREXLYWEL SXLTXXIXEL GPYXLDRXSL  
 20301 YVNG<sup>2</sup>XXXXXXXX<sup>2</sup> XXXTST<sup>2</sup>PGTS XVXLXTSGTP XXXPXX<sup>2</sup>TAPV PLLIPFTLNF  
 20351<sup>188</sup> TITNLHYEEN MOHPGRSRKF<sup>2</sup>N TTERVLQGI<sup>213</sup> RPLFKSTSVG PLYSGCRLTL  
 20401 L<sup>242</sup>PEKHGAAT GVDAICTLRL DPTGPGLDRE RLYWELS<sup>2</sup>QLT NSVTELGPYT  
 20451 LDRDSLYVNG<sup>273</sup> FTQRSSVPTT SI<sup>290</sup>PGTSAVHL ETSGTPASLP GHT<sup>2</sup>APGPLLV  
 20501<sup>169</sup> PFTLNFTITN LOYEVD<sup>2</sup>MRHP GSRKFNTT<sup>2</sup>ER VLQGI<sup>198</sup>LKPLF KSTSVGPLY  
 20551<sup>239</sup> GCRLTLLR<sup>2</sup>PE KRGAA<sup>2</sup>TGVDT ICTHRLDPLN PGLDREQLYW ELSKLTRGII

20601 ELGPYLLDRG SLYVNG<sup>200</sup>ETHR NFVPITST<sup>292</sup>PG TSTVHLGTSE TPSSLPRT<sup>160</sup>V  
 20651 PGPLLVPFTL<sup>212</sup> N<sup>160</sup>FTITNLQYE EAMRH<sup>247</sup>PGSRK ENT<sup>247</sup>TERVLOG I<sup>247</sup>LRPLFKNTS  
 20701 IGPLYSSCRL<sup>212</sup> TLL<sup>247</sup>RPEKDKA ATRVDAICTH HPDPQSPGLN<sup>247</sup> REQLYWEL<sup>293</sup>LSQ  
 20751 LTHGITELGP YTLDRDSLYV D<sup>268</sup>QETHWSPIP TTST<sup>2</sup>PGTSIV NLGTSGIPPS  
 20801 LPETT<sup>198</sup>XXXPL LXPFTLNFTI<sup>2</sup> TNLXYEEXMX XPGSRKFNTT ERVLOGI<sup>233</sup>LKP  
 20851 LFKSTSVGPL YSGCRLTLLR<sup>198</sup> PEKDG<sup>274</sup>VATRV DAICTHRPDP KIPGLDRQOL  
 20901 YWELSQLTHS ITELGPYTLD RDSLYVNG<sup>274</sup>FT QRSSVPTTST<sup>274</sup> PGFTTVQPET  
 20951 SETPSSLPGP<sup>294</sup> TATGPVLLPF<sup>294</sup> TLNFTITNLQ<sup>181</sup> YEEDMHRPGS RKFNTTERVL  
 21001 OGIL<sup>220</sup>MPLEFKN TSVSSLYSGC RLTL<sup>232</sup>LRPEKD GAATRVDAVC THRPDPKSPG  
 21051 LDRERLYWKL<sup>232</sup> SQLTHGITEL GPYTLDRA<sup>260</sup>SL YVNG<sup>260</sup>ETHQSS MTTTR<sup>260</sup>TPOTS  
 21101 TMHLATSRT<sup>289</sup>P ASLSGPT<sup>289</sup>AS PLLVLETINF<sup>185</sup> TITNLRYEEN MHRPGSRKFEN  
 21151 TTERVLOGIL<sup>215</sup> RPVFKN<sup>215</sup>TSVG PLYSGCRLTL L<sup>215</sup>RPKKDGAAT KVDAICTYRP  
 21201 DPKSPGLDRE<sup>231</sup> QLYWELSQLT<sup>231</sup> HSITELGPYT QDRDSLYNVG<sup>275</sup> FTQRSSVPTT  
 21251 SV<sup>295</sup>PGTPTVDL<sup>295</sup> GTSGTPVSKP GPS<sup>190</sup>AAPELLV LFTLNGTITN LRYEENMQHP  
 21301 GSRKFNTTER VLOGI<sup>210</sup>LRSLE KSTSVGPLY<sup>210</sup>YS GCRLTLL<sup>210</sup>RPE KDGTATGVDA  
 21351 ICTHHPDPKS<sup>225</sup> PRLDREQLYW ELSQLTHNIT ELGHYALDND SLFVNG<sup>225</sup>ETHR  
 21401<sup>255</sup> SSVSTTST<sup>290</sup>PG TPTVYL<sup>290</sup>GASK TPASIFGPS<sup>192</sup> ASHLLILETL N<sup>192</sup>FTITNLRYE  
 21451 ENMWPGSRKF<sup>211</sup> NTTERVLQGL<sup>211</sup> LRPLFKNTSV<sup>211</sup> GPLYSGSRLT LLR<sup>211</sup>PEKDGEA  
 21501 TGVDAICTHR<sup>220</sup> PDPTGPG<sup>220</sup>LDR EQLYLELSQL THSITELGPY TLD<sup>220</sup>RDSLYVN  
 21551<sup>254</sup> ETHRSSVPT<sup>254</sup> TS<sup>193</sup>IGVVSEEP FTLNFTINN<sup>193</sup>L RYMADMGQPG SLKFNITDNV  
 21601 MKHIL<sup>209</sup>SPLEFQ RSSLGARYTG CRVIAL<sup>209</sup>FSVK NGAETRVDLL CTYLOPLSGP  
 21651 GLPIKQVFHE<sup>248</sup> LSQOTHG<sup>248</sup>ITR LGPYS<sup>270</sup>LDKDS LYLN<sup>270</sup>GKNEPG LDEPPT<sup>270</sup>TPKP  
 21701<sup>297</sup> ATTFLPPLSE<sup>297</sup> ATT<sup>194</sup>MGYHLK TLTLNFTISN<sup>194</sup> LQYSPDMGKG SATFNSTEGV  
 21751<sup>221</sup> LOHL<sup>221</sup>LRPLEFQ KSSMGPFYLG CQLISLR<sup>221</sup>PEK DGAATGVDDT CTYHPDFVGP  
 21801<sup>249</sup> GLDIQQLYWE<sup>249</sup> LSQLTHGVTQ LGFYVLDROS L<sup>249</sup>FING<sup>249</sup>KAPON LSIRGEY<sup>249</sup>QIN  
 21851<sup>298</sup> FHIVNWNLSN<sup>298</sup> PDPTSSEY